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Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20857-003

RE: Docket No. 98N-1265

To whom it may concern:

This legislation is a **LIFE or DEATH** situation for me. The FDA drafted MOU intended to provide legislative guidance to State Agencies (FDA Modernization Act of 1997, Section 503A). This MOU, as written, severely limits the practice and interstate distribution of compounded drugs.

I have a thyroid condition called Wilson's Syndrome. The medication for this condition is T3SR, a specially compounded thyroid medication that can only be obtained from seven pharmacy labs in the US. I currently receive it from Apothecure Pharmacy in Dallas, TX. There is no pharmacy in South Dakota that compounds T3SR.

Without this medication, I CAN NOT LIVE! My thyroid does not work at all. My cells can not utilize Synthroid to change it to T3 that the cells can use. Therefore, I must have the direct T3SR that the cells can use. As you probably know, the thyroid is the master gland that regulates all the systems of the body. Without T3SR (Sustained Release), my body temperature goes lower and lower and my whole body starts to shut down. Therefore, I must have T3SR which I must get from out of state.

For more information on Wilson Syndrome, log onto the internet at: www.wilsonssyndrome.com. Some doctors have estimated that as many as 30 % of our population have symptoms consistent with Wilson's Syndrome and would respond to the T3SR therapy.

Please withdraw or amend this MOU. Many consumers and doctors would no longer have access to some compounded drugs that are currently used as effective treatments. For those being treated for Wilson's Syndrome, this MOU as written will mean **DEATH!**

Sincerely,

Leverly of Warns
Beverly J. Warns

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RONALD W. OR BEVERLY J. WARNS 2503 COUNTRY ESTATES DR. MADISON, SD 57042





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RE: Docket # 98N-1245

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